IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joachim Hauber, et al. Examiner: Unassigned

Serial No.: Unassigned Art Unit: Unassigned

Filing Date: Herewith Docket: 15120

For: COMPOUNDS THAT AFFECT CD83 Date: December 19, 2001

EXPRESSION, PHARMACEUTICAL COMPOSITIONS COMPRISING SAID COMPOUNDS AND METHODS FOR **IDENTIFYING SAID COMPOUNDS**

Assistant Commissioner for Patents Washington, DC 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination, please amend the above-identified patent application as

follows:

IN THE CLAIMS:

Please cancel Claims 23 and 26 without prejudice.

Please amend the following claims:

2. (Amended) The compound according to claim 1, wherein said compound

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" mailing label number: EV052766852US

Date of Deposit: December 19, 2001

I hereby certify that this New Patent Application and Fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

Dated: December 19, 2001

Janet Grossman

comprises a nucleic acid.

- 3. (Amended) The compound according to claim 2, wherein said compound comprises DNA.
- 4. (Amended) The compound according to claim 2, wherein said compound comprises RNA.
- 5. (Amended) The compound according to claim 2 wherein said compound contains at least a portion of the coding region of a member of the CD83 family of proteins or a derivative thereof.
- 6. (Amended) The compound according to claim 2 wherein said compound contains from nucleotide 466 to 618 of the sequence in SEQ ID NO:1 or a derivative thereof.
- 7. (Amended) The compound according to claim 2 wherein said compound contains from nucleotide 466 to 615 of the sequence in SEQ ID NO:1 or a derivative thereof.
- 8. (Amended) The compound according to claim 2 wherein said compound contains a nucleic acid having a secondary structure comprising a 3-pronged stem-loop structure with an energy of –28.4 kcal/mol or less.
- 9. (Amended) The compound according to claim 2 wherein said compound is a nucleic acid that comprises regulatory sequences that lead to the transcription of an RNA molecule from said nucleic acid in a cell.
- 10. (Amended) The compound according to claim 2 wherein said compound is a nucleic acid that does not contain regulatory sequences that lead to the translation of a polypeptide or protein from said nucleic acid in a cell.
- 11. (Amended) The compound according to claim 1, wherein said compound comprises a protein.

- 12. (Amended) The compound according to claim 11, wherein said protein is a derivative of members of the ELAV superfamily of proteins.
- 13. (Amended) The compound according to claim 12, wherein said protein is selected from the group consisting of ELAV, Hur, Hub, HuC, HuD, HuDpro, HuDmex, Hel-N2 and HuC isoforms, Rel-N1 and naturally occurring homologues of said proteins.
- 14. (Amended) The compound according to claim 11, wherein said protein is a derivative of a protein ligand to HuR.
- 15. (Amended) The compound according to claim 14, wherein said protein is selected from the group consisting of SET α , SET β , pp32 and APRIL and naturally occurring homologues of said proteins.
- 16. (Amended) A pharmaceutical composition comprising a compound according to claim 1.
- 17. (Amended) A method of treating or preventing disease involving the direct or indirect participation of Dendritic Cells (DC) comprising the administration of a pharmaceutical composition to a patient in need thereof comprising a compound according to claim 1.
- 18. (Amended) The method according to claim 17, wherein said disease involves the growth, differentiation and/or activation of cytotoxic T cells and helper T cells.
- 19. (Amended) The method according to claim 17, wherein said disease is selected from the group consisting of allergies, asthma, autoimmune syndromes such as myasthemia gravis, multiple sclerosis and systemic lupus erythematosis, skin diseases such as psoriasis, rheumatoid arthritis and AIDS.

- 20. (Amended) A method of treating or preventing rejection of a tissue or organ transplant comprising the administration of a pharmaceutical composition to a patient in need thereof comprising a compound according to claim 1.
- 27. (Amended) A method for screening and/or identifying compounds that block the binding between a member of the HuR family of proteins and a mRNA encoding a member of the CD83 family of proteins comprising the steps of incubating one or more compounds in a reaction comprising:
- (a) a nucleic acid molecule that contains at least a portion of the coding region of a member of the CD83 family of proteins or a derivative thereof and;
- (b) a member of the ELAV superfamily of proteins or derivative thereof
 under conditions sufficient to allow the components to interact and determining
 whether the compound blocks the binding between the nucleic acid molecule and the member of
 the ELAV superfamily of proteins.
- 28. (Amended) The method according to claim 27, wherein said member of the CD83 family of proteins is CD83.
- 29. (Amended) The method according to claim 28, wherein said member of the ELAV superfamily of proteins is selected from the group consisting of ELAV, HuR, HuB, HuC, HuD, HuDpro, HuDmex, Hel-N2 and HuC isoforms, Rel-N1 and naturally occurring homologues of these proteins.
- 30. (Amended) The method according to Claim 29, characterized in that said method is carried out in the form of an assay selected from the group consisting of RNA gel shift assay, filter binding assay, Biacore interaction analysis, Scintilation Proximity Assay, RNAse protection assay, cell-based RNA binding assay, yeast 3-hybrid assays and reporter gene assay.

- 31. (Amended) A method for producing a pharmaceutical composition comprising a compound that blocks the binding between a member of the HuR family of proteins and a mRNA encoding a member of the CD83 family of proteins when incubated in a reaction comprising combining:
- (a) a nucleic acid molecule that contains at least a portion of the coding region of a member of the CD83 family of proteins or a derivative thereof and
- (b) a member of the ELAV superfamily of proteins or derivative thereof under conditions sufficient to allow the components to interact, wherein said composition treats or prevents disease involving the direct or indirect participation of dendritic cells (DC).

Please add the following new claims:

- 32. (New) The compound according to claim 2 wherein said compound contains a nucleic acid having a secondary structure comprising a 3-pronged stem-loss structure with an energy of -29.7 kcal/mol or less.
- 33. (New) The method according to claim 17, wherein said disease involves the differention of helper T cells into Th1 cells or Th2 cells.
- 34. (New) The method according to claim 17, wherein said disease involves the growth, stimulation and/or differention of B cells.

REMARKS

It is respectfully requested that this Preliminary Amendment be entered in this application prior to examination. Early and favorable consideration is requested.

Respectfully submitted,

Leopoid Presser Registration No. 19,827

SCULLY, SCOTT, MURPHY & PRESSER 400 Garden City Plaza Garden City, New York 11530 (516) 742-4343

PIB:bg

U.S. Serial No.: Unassigned Docket: 15120

New Patent Application

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please cancel Claims 23 and 26 without prejudice.

Please amend the following claims:

- 2. (Amended) [A] <u>The</u> compound according to claim 1, [characterized in that] <u>wherein</u> said compound comprises a nucleic acid.
- 3. (Amended) [A] <u>The</u> compound according to claim [1 or] 2, [characterized in that the] <u>wherein said</u> compound comprises DNA.
- 4. (Amended) [A] <u>The</u> compound according to claim [1 or] 2, [characterized in that the] wherein said compound comprises RNA.
- 5. (Amended) [A] <u>The</u> compound according to [any of the preceding claims, characterized in that the] <u>claim 2 wherein said</u> compound contains at least a portion of the coding region of a member of the CD83 family of proteins or a derivative thereof.
- 6. (Amended) [A] <u>The</u> compound according to [any of the preceding claims, characterized in that the] <u>claim 2 wherein said</u> compound contains from nucleotide 466 to 618 of the sequence in SEQ ID NO:1 or a derivative thereof.
- 7. (Amended) [A] <u>The</u> compound according to [any of the preceding claims, characterized in that the] <u>claim 2 wherein said</u> compound contains from nucleotide 466 to 615 of the sequence in SEQ ID NO:1 or a derivative thereof.
- 8. (Amended) [A] <u>The</u> compound according to [any of the preceding claims, characterized in that the] <u>claim 2 wherein said</u> compound contains a nucleic acid having a

secondary structure comprising a 3-pronged stem-loop structure with an energy of -28.4 kcal/mol or less[; preferably -29.7 kcal/mol or less].

- 9. (Amended) [A] <u>The</u> compound according to [any of the preceding claims, characterized in that the] <u>claim 2 wherein said</u> compound is a nucleic acid that comprises regulatory sequences that lead to the transcription of an RNA molecule from said nucleic acid in a cell.
- 10. (Amended) [A] <u>The</u> compound according to [any of the preceding claims, characterized in that the] <u>claim 2 wherein said</u> compound is a nucleic acid that does not contain regulatory sequences that lead to the translation of a polypeptide or protein from said nucleic acid in a cell.
- 11. (Amended) [A] <u>The</u> compound according to claim 1, [characterized in that] <u>wherein</u> said compound comprises a protein.
- 12. (Amended) [A] <u>The</u> compound according to claim 11, [characterized in that] <u>wherein</u> said protein is a derivative of members of the ELAV superfamily of proteins.
- 13. (Amended) [A] <u>The</u> compound according to claim 12, [characterized in that] <u>wherein</u> said protein is selected from the group [of proteins] consisting of ELAV, Hur, Hub, HuC, HuD, HuDpro, HuDmex, Hel-N2 and HuC isoforms, Rel-N1 and naturally occurring homologues of [these] <u>said</u> proteins.
- 14. (Amended) [A] <u>The</u> compound according to claim 11, [characterized in that] <u>wherein</u> said protein is a derivative of a protein ligand to HuR.
- 15. (Amended) [A] <u>The</u> compound according to claim 14, [characterized in that] <u>wherein</u> said protein is selected from the group [of proteins] consisting of SET α , SET β , pp32 and APRIL [as well as] <u>and</u> naturally occurring homologues of [these] <u>said</u> proteins.

- 16. (Amended) A pharmaceutical composition comprising a compound according to [any of claims 1 to 15] claim 1.
- 17. (Amended) [The use of a compound according to any of claims 1 to 15 for the production of a pharmaceutical composition] A method of [for] treating or preventing disease involving the direct or indirect participation of Dendritic Cells (DC) [DC] comprising the administration of a pharmaceutical composition to a patient in need thereof comprising a compound according to claim 1.
- 18. (Amended) The [use] method according to claim 17, [characterized in that] wherein said disease [is selected from the group consisting of diseases involving] involves the growth, differentiation and/or activation of cytotoxic T cells and helper T cells[, the differentiation of helper T cells into Th1 cells or Th2 cells, the growth, stimulation and/or differentiation of B cells].
- 19. (Amended) The [use] method according to claim 17, [characterized in that] wherein said disease is selected from the group consisting of allergies, asthma, autoimmune syndromes such as myasthemia gravis, multiple sclerosis and systemic lupus erythematosis, skin diseases such as psoriasis, rheumatoid arthritis and AIDS.
- 20. (Amended) [The use of a compound a compound according to any of claims 1 to 15 for the production of a pharmaceutical composition for] A method of treating or preventing rejection of a tissue or organ transplant comprising the administration of a pharmaceutical composition to a patient in need thereof comprising a compound according to claim 1.
- 27. (Amended) A method for screening and/or identifying compounds that block the binding between a member of the HuR family of proteins and a mRNA encoding a member

of the CD83 family of proteins comprising the steps of incubating one or more compounds in a reaction comprising:

- (a) a nucleic acid molecule that contains at least a portion of the coding region of a member of the CD83 family of proteins or a derivative thereof and;
- (b) a member of the ELAV superfamily of proteins or derivative thereof
 under conditions sufficient to allow the components to interact and determining
 whether the compound blocks the binding between the nucleic acid molecule and the member of
 the ELAV superfamily of proteins.
- 28. (Amended) <u>The</u> method according to claim 27, [characterized in that the] wherein said member of the CD83 family of proteins is CD83.
- 29. (Amended) The method according to claim [27 or] 28, [characterized in that the] wherein said member of the ELAV superfamily of proteins is selected from the group consisting of ELAV, HuR, HuB, HuC, HuD, HuDpro, HuDmex, Hel-N2 and HuC isoforms, Rel-N1 and naturally occurring homologues of these proteins.
- 30. (Amended) The method according to [any of claims 27 to] Claim 29, characterized in that said method is carried out in the form of an assay selected from the group consisting of RNA gel shift assay, filter binding assay, Biacore interaction analysis, Scintilation Proximity Assay, RNAse protection assay, cell-based RNA binding assay, yeast 3-hybrid assays and reporter gene assay.
- 31. (Amended) [Use of] <u>A method for producing a pharmaceutical composition</u> comprising a compound that blocks the binding between a member of the HuR family of proteins and a mRNA encoding a member of the CD83 family of proteins when incubated in a reaction comprising combining:

- (a) a nucleic acid molecule that contains at least a portion of the coding region of a member of the CD83 family of proteins or a derivative thereof and
- (b) a member of the ELAV superfamily of proteins or derivative thereof under conditions sufficient to allow the components to interact, [for the production of a pharmaceutical composition for treating or preventing] wherein said composition treats or prevents disease involving the direct or indirect participation of dendritic cells (DC).

Please add the following new claims:

- 32. (New) The compound according to claim 2 wherein said compound contains a nucleic acid having a secondary structure comprising a 3-pronged stem-loss structure with an energy of -29.7 kcal/mol or less.
- 33. (New) The method according to claim 17, wherein said disease involves the differention of helper T cells into Th1 cells or Th2 cells.
- 34. (New) The method according to claim 17, wherein said disease involves the growth, stimulation and/or differention of B cells.